

Facility ID: 0125041763 Issuance type: Final State Permit To Operate

This version of facility specific terms and conditions was converted from a database format to an HTML file during an upgrade of the Ohio EPA, Division of Air Pollution Control's permitting software. Every attempt has been made to convert the terms and conditions to look and substantively conform to the permit issued or being drafted in STARS. However, the format of the terms may vary slightly from the original. In addition, although it is not expected, there is a slight possibility that a term and condition may have been inadvertently "left out" of this reproduction during the conversion process. Therefore, if this version is to be used as a starting point in drafting a new version of a permit, it is imperative that the entire set of terms and conditions be reviewed to ensure they substantively mimic the issued permit. The official version of any permit issued final by Ohio EPA is kept in the Agency's Legal section. The Legal section may be contacted at (614) 644-3037.

In addition to the terms and conditions, hyperlinks have been inserted into the document so you may more readily access the section of the document you wish to review.

Finally, the term language under "Part II" and before "A. Applicable Emissions Limitations..." has been added to aid in document conversion, and was not part of the original issued permit.

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Facility ID: 0125041763 Emissions Unit ID: P002 Issuance type: Final State Permit To Operate

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Part II - Special Terms and Conditions

This permit document constitutes a permit-to-install issued in accordance with ORC 3704.03(F) and a permit-to-operate issued in accordance with ORC 3704.03(G).

1. For the purpose of a permit-to-install document, the emissions unit terms and conditions identified below are federally enforceable with the exception of those listed below which are enforceable under state law only.
 - (a) None.
2. For the purpose of a permit-to-operate document, the emissions unit terms and conditions identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.
 - (a) None.

A. Applicable Emissions Limitations and/or Control Requirements

1. The specific operation(s), property, and/or equipment which constitute this emissions unit are listed in the following table along with the applicable rules and/or requirements and with the applicable emissions limitations and/or control measures. Emissions from this unit shall not exceed the listed limitations, and the listed control measures shall be employed. Additional applicable emissions limitations and/or control measures (if any) may be specified in narrative form following the table.

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>	<u>Applicable Emissions Limitations/Control Measures</u>
pharmaceutical manufacturing and packaging operation	OAC rule 3745-17-07(A)(1)	The particulate emissions (PE) limit established by OAC rule 3745-17-07(A)(1) is less stringent than those established under OAC rule 3745-31-05(A)(3).
	OAC rule 3745-17-11(C)	See section A.2.b below. The PE limit established by OAC rule 3745-17-11(C) is less stringent than those established under OAC rule 3745-31-05(A)(3).
	OAC rule 3745-31-05(A)(3) (PTI 01-08002)	Particulate emissions (PE) shall not exceed 0.10 lb/hr and 0.10 ton/yr.
		Organic compound (OC) emissions shall not exceed 10 lbs/hr and 5.5 tons/yr.
		See sections A.2.a, A.2.b and B.1 below.
		The requirements of this rule shall also include compliance with the requirements of OAC rules 3745-21-07(G)(9), OAC rule 3745-17-11(C) and OAC rule 3745-17-07(A).
	OAC rule 3745-21-07(G)(9)	See section A.2.c below.

2. Additional Terms and Conditions

- (a) The emissions unit shall vent to a baghouse, pleated filter and a HEPA (high-efficiency particulate air) filter with an in-series composite control efficiency of 99.99%. This control equipment is considered an inherent physical limitation since the filtration system is used to ensure that the company can account for the pharmaceutical powder utilized in each batch, by weight. The FDA and DEA require total accountability of the pharmaceuticals manufactured in this process. Due to the inherent physical limitation, monitoring for visible emissions is unnecessary. There shall be no visible emissions from the emissions unit. The permittee shall not use any photochemically reactive materials as defined in OAC rule 3745-21-01(C)

B. Operational Restrictions

1. The permittee shall not employ an alcohol with an organic compound content of greater than 98% by weight.

C. Monitoring and/or Record Keeping Requirements

1. The permittee shall maintain daily records of the following information:
 - a. the number of gallons of alcohol employed;
 - b. the density of the alcohol, in pounds per gallon;
 - c. the percent of organic compounds, by weight;

- d. the total number of hours the emissions units was in operation;
 - e. the total uncontrolled organic compound emissions, in pounds per day; and
 - f. the average hourly uncontrolled organic compound emission rate for alcohol, in pounds per hour (average).
2. The permittee shall maintain daily records that document any time when the baghouse, pleated filter and/or HEPA filter were not in service while the emissions unit was in operation.
 3. The permit to install for this emissions unit P002 was evaluated based on the actual materials and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") was applied to this emissions unit for each toxic pollutant, using data from the permit to install application, and modeling was performed for the toxic pollutant(s) emitted at over a ton per year using the SCREEN 3.0 model or other Ohio EPA approved model. The predicted 1-hour maximum ground-level concentration result(s) from the use of the SCREEN 3.0 (or other approved) model, was compared to the Maximum Acceptable Ground-Level Concentration (MAGLC), calculated as required in Engineering Guide #70. The following summarizes the results of the modeling for the "worst case" pollutant(s):

Pollutant: Ethyl alcohol
 TLV (mg/m3): 1,880,000
 Maximum Hourly Emission Rate (lbs/hr): 8.7
 Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 1,275
 MAGLC (ug/m3): 44,762

4. Physical changes to or changes in the method of operation of the emissions unit after its installation or modification could affect the parameters used to determine whether or not the "Air Toxic Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will still be satisfied. If, upon evaluation, the permittee determines that the "Air Toxic Policy" will not be satisfied, the permittee will not make the change. Changes that can affect the parameters used in applying the "Air Toxic Policy" include the following:
 - a. changes in the composition of the materials used or the use of new materials, that would result in the emission of a compound or chemical with a lower Threshold Limit Value (TLV) than the lowest TLV previously modeled, as documented in the most current version of the American Conference of Governmental Industrial Hygienists' (ACGIH's) handbook entitled "TLVs and BEIs" ("Threshold Limit Values for Chemical Substances and Physical Agents, Biological Exposure Indices");
 - b. changes in the composition of the materials, or use of new materials, that would result in an increase in emissions of any pollutant with a listed TLV that was proposed in the application and modeled; and
 - c. physical changes to the emissions unit or its exhaust parameters (e.g., increased/decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).
5. If the permittee determines that the "Air Toxic Policy" will be satisfied for the above changes, the Ohio EPA will not consider the change(s) to be a "modification" under OAC rule 3745-31-01 solely due to the emissions of any type of toxic air contaminant not previously emitted, and a modification of the existing permit to install will not be required, even if the toxic air contaminant emissions are greater than the de minimis level in OAC rule 3745-15-05. If the change(s) meet(s) the definition of a "modification" under other provisions of the rule, then the permittee shall obtain a final permit to install prior to the change.

The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that the changed emissions unit will still satisfy the "Air Toxic Policy":

- a. a description of the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.);
- b. documentation of the evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and
- c. where computer modeling is performed, a copy of the resulting computer model runs that show the results of the application of the "Air Toxic Policy" for the change.

D. Reporting Requirements

1. The permittee shall submit deviation (excursion) reports which identify each day during which the average hourly total organic compound emissions exceeded 10 pounds per hour and the actual average hourly organic compound emissions for each such day. The quarterly deviation reports shall be submitted in accordance with the General Terms and Conditions of this permit.
2. The permittee shall notify the Central District Office in writing of any daily record that identify each day during which any photochemically reactive materials were employed in this emissions unit. The notification shall include a copy of such record and shall be sent to the Central District Office within 30 days after the event occurs.
3. The permittee shall submit an annual report which specifies the organic compound emissions for the previous calendar year. These reports shall be submitted by January 31 of each year.
4. The permittee shall notify the Central District Office in writing of any daily record showing that the dust collector, pleated filter and/or HEPA filter were not in service when the emissions unit was in operation. The notification shall include a copy of such record and shall be sent to the Central District Office within 30 days after the event occurs.

E. Testing Requirements

1. Compliance with the emissions limitations in Section A.1 of these terms and conditions shall be determined in accordance with the following methods:

Emission Limitation:

There shall be no visible emissions from the emissions unit.

Applicable Compliance Method:

If required, compliance shall be determined through visible emissions observations performed in accordance with 40 CFR Part 60, Method 22 and the procedures specified in OAC rule 3745-17-03(B)(4).

Emission Limitation:

PE shall not exceed 0.1 lb/hr and 0.1 ton/yr.

Applicable Compliance Method:

Compliance with the hourly emission limitation shall be demonstrated by multiplying the maximum hourly solids usage of 793 pounds per hour by the non-recovered product loss of 0.25 (emission factor determined by company mass balance) and 0.0001 (control efficiency). The annual limitation was established by multiplying the hourly emission limitation by the maximum possible annual operating hours (8760 hrs/yr) and dividing by 2000 lbs/ton. Therefore, compliance with the annual emission limitation shall be assumed provided compliance is maintained with the hourly emission limitation.

Emission Limitation:

Organic compound emissions shall not exceed 10.0 lbs/hr .

Applicable Compliance Method:

Compliance shall be demonstrated by multiplying the density of the alcohol by the daily alcohol usage (in gallons) and the percent of organic compounds, by weight, and then dividing by the hours of operation.

Formulation data derived from MSDS or USEPA Method 24 shall be used to determine the organic compound content of the alcohol.

Emission Limitation:

Organic compound emissions shall not exceed 5.5 tons per year.

Applicable Compliance Method:

Compliance shall be demonstrated by the summing the total uncontrolled organic compound emissions, in pounds per day, and then adding the emissions from the previous eleven months and converting to tons per year.

F. **Miscellaneous Requirements**

1. None

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Part II - Special Terms and Conditions

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1. For the purpose of a permit-to-install document, the emissions unit terms and conditions identified below are federally enforceable with the exception of those listed below which are enforceable under state law only.
 - (a) None.
2. For the purpose of a permit-to-operate document, the emissions unit terms and conditions identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.
 - (a) None.

A. **Applicable Emissions Limitations and/or Control Requirements**

1. The specific operation(s), property, and/or equipment which constitute this emissions unit are listed in the following table along with the applicable rules and/or requirements and with the applicable emissions limitations and/or control measures. Emissions from this unit shall not exceed the listed limitations, and the listed control measures shall be employed. Additional applicable emissions limitations and/or control measures (if any) may be specified in narrative form following the table.

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>	<u>Applicable Emissions Limitations/Control Measures</u>
Fluid bed dryer/granulator	OAC rule 3745-17-07(A)(1)	The particulate emissions (PE) limit established by OAC rule 3745-17-07(A)(1) is less stringent than those established under OAC rule 3745-31-05(A)(3).
	OAC rule 3745-17-11(C)	See section A.2.a below. The PE limit established by OAC rule 3745-17-11(C) is less stringent than those established under OAC rule 3745-31-05(A)(3).
	OAC rule 3745-31-05(A)(3) (PTI 01-6309)	PE shall not exceed 0.35 lb/hr and 1.52 tons/yr.
		See sections A.2.a, A.2.b and A.2.c below. The requirements of this rule shall also include

compliance with the requirements of OAC rules 3745-21-07(G)(9), OAC rule 3745-17-11(C) and OAC rule 3745-17-07(A).

2. **Additional Terms and Conditions**

- (a) There shall be no visible emissions from the emissions unit.
The 0.35 lb PE limitation for this emissions unit was established to reflect the maximum potential to emit. Therefore, it is not necessary to develop additional monitoring, record keeping and/or reporting requirements to ensure compliance with this limitation.
The emissions unit shall vent to a baghouse, pleated filter and a HEPA (high-efficiency particulate air) filter with an in-series composite control efficiency of 99%. This control equipment is considered an inherent physical limitation since the filtration system is used to ensure that the company can account for the pharmaceutical powder utilized in each batch, by weight. The FDA and DEA require total accountability of the pharmaceuticals manufactured in this process. Due to the inherent physical limitation, monitoring for visible emissions is unnecessary.

B. **Operational Restrictions**

1. None

C. **Monitoring and/or Record Keeping Requirements**

1. The permittee shall maintain daily records that document any time when the baghouse, pleated filter and/or HEPA filter were not in service while the emissions unit was in operation.

D. **Reporting Requirements**

1. The permittee shall notify the Central District Office in writing of any daily record showing that the dust collector, pleated filter and/or HEPA filter were not in service when the emissions unit was in operation. The notification shall include a copy of such record and shall be sent to the Central District Office within 30 days after the event occurs.

E. **Testing Requirements**

1. Compliance with the emissions limitations in Section A.1 of these terms and conditions shall be determined in accordance with the following methods:

Emission Limitation:

There shall be no visible emissions from the emissions unit.

Applicable Compliance Method:

If required, compliance shall be determined through visible emissions observations performed in accordance with 40 CFR Part 60, Method 22 and the procedures specified in OAC rule 3745-17-03(B)(4).

Emission Limitation:

PE shall not exceed 0.35 lb/hr and 1.52 tons/yr.

Applicable Compliance Method:

Compliance with the hourly emission limitation shall be demonstrated by multiplying the maximum hourly solids usage of 693 pounds per hour by the non-recovered product loss of 0.05 (emission factor determined by company mass balance) and 0.01 (control efficiency). The annual limitation was established by multiplying the hourly emission limitation by the maximum possible annual operating hours (8760 hrs/yr) and dividing by 2000 lbs/ton. Therefore, compliance with the annual emission limitation shall be assumed provided compliance is maintained with the hourly emission limitation.

F. **Miscellaneous Requirements**

1. None